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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,666	02/08/2002	Gyanendra Kumar	13172.0015U1	3290

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,666	KUMAR ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) *137 and 138* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/15/04; 5/19/03; 6/16/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment filed on August 4, 2004 has been entered.

2. Claims 1-138 are pending Claims 137-138 are withdrawn.

3. This application is filed on February 8, 2002.

Response to Arguments

4. Applicant's response to the office action is fully considered and is found persuasive.

5. With regard to the rejection made in the previous office action under 35 USC 102(e), Applicants' arguments and amendment are fully considered and found persuasive in view of the arguments regarding the decoupling step, and new grounds of rejections.

6. With regard to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments and amendment are fully considered and found persuasive in view of the arguments regarding the decoupling step, and new grounds of rejections.

7. With regard to the rejection made in the previous office action under double patenting, Applicants' arguments and amendment are fully considered and found persuasive in view of the arguments regarding the decoupling step, and new grounds of rejections.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingsmore et al. (USPN. 6,531,283) and in view of Lizardi et al. (USPN.5,854,033).

With reference to the instant claims 1, 30, 43-49, 107, 124-126, 133-136, Kingsmore et al. teach a method for detecting one or more analytes comprising (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes (see column 41, lines 33-55); (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a single-stranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers (see column 41, lines 56-67); (d) incubating the rolling circle primers and

amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes (see column 42, lines 32-39).

With reference to the instant claims 12-22, Kingsmore et al. teach that the method comprises circle linkers (capture docks), wherein circle linker comprises cleavable bond which could be a disulfide bond, hetero bifunctional succinimide bond (sulfo-GMBS) maleimide bond, dihydroxy bond or amino linking group (reactive group) which can be cleavable by treatment with a reducing agent (see column 14, lines 25-67, column 15, lines 1-4, column 30, lines 4-10).

With reference to the instant claims 23-29, Kingsmore et al. also teach that the method comprises (i) plurality of reporter binding molecules are brought into contact with the one or more analyte samples (see column 42, lines 40-42); (ii) plurality of analyte samples are brought into contact with the one or more reporter binding molecules (see column 42, lines 43-45); (iii) at least one of the analyte samples comprise a protein or peptide, a lipid, glycolipid or proteoglycan (see column 42, lines 46-49); (iv) at least one of the analytes is from a human source and a non-human source (see column 42, lines 50-53); and none of the analytes are nucleic acids (see column 42, lines 54-55);

With reference to the instant claims 31-32, 35, Kingsmore et al. teach that the method comprises capture agent(s) and analyte(s) associated with a solid support and the solid support comprises different reaction chambers or predefined regions (see column 42, lines 61-67); the said solid support comprises acrylamide, agarose, cellulose, nitrocellulose, glass, polystyrene or polyamino acids (see column 43, lines 29-37);

With reference to the instant claims 36-42, Kingsmore et al. also disclose that the method comprises (i) bringing into contact at least one of the analyte samples with at least one accessory molecule affecting interaction of at least one of the analytes and at least one of the capture agents simultaneously with or following step (a) (see column 43, lines 39-48); (ii) at least one analyte and accessory molecule are associated with the solid support simultaneously with or following step(a) (see column 43, lines 49-55); (iii) the accessory molecule is a protein kinase, a protein phosphatase, an enzyme or a compound (see column 43, lines 56-58); (iv) interaction of accessory molecule of interest, with one or more analytes are test molecules of interest are detected (see column 43, lines 59-65);

With reference to the instant claims 43-75, Kingsmore et al. also teach that the method comprises (i) one or more first analyte samples and one or more second analyte samples, one or more first reporter binding molecules, one or more second reporter molecules, wherein each different reporter binding molecule is different and each different rolling circle primer primes replication of a different amplification target circle and produces a different tandem sequence DNA (see column 44, lines 9-43); (ii) the tandem sequence DNA corresponding to one of the analyte samples produced in association with an analyte capture agent is in the same location on the solid support as tandem sequence DNA corresponding to the same analyte and produced in association with the matching second analyte capture agent, wherein presence or absence of the same analyte in different analyte samples is indicated by the presence or absence of corresponding tandem sequence DNA (see column 44, lines 53-67, column 45, lines 1-5); (iii) at least one analyte and accessory molecule are associated with the solid support simultaneously with or following step(a) (see column 45, lines 6-55); (iii) the accessory molecule is a protein

kinase, a protein phosphatase, an enzyme or a compound (see column 45, lines 36-38); (iv) the accessory molecule is an analog and facilitates interaction of at least one of the analyte capture agents (see column 45, lines 27-35); accessory molecule is at least 20%, 50% , 80%, 90% pure and is associated with solid support (see column 45, lines 39-47);

With reference to the instant claims 76-83, Kingsmore et al. teach that the method comprises modified form of analyte wherein at least one or more analyte capture agents interacts directly or indirectly with the modified analyte, wherein the modification is post-translational modification, that is phosphorylation or glycosylation (see column 45, lines 55-65); detection of tandem sequence DNA is accompanied by mixing a set of detection probes under conditions to promote hybridization, wherein plurality of different tandem sequence DNAs are detected separately or simultaneously via multiplex detection (see column 45, lines 66-67, column 46, lines 1-7); detection probes are labeled using combinatorial multicolor coding (see column 46, lines 8-9); the method further comprises brining into contact a secondary DNA strand displacement primer and the tandem sequence DNA, and incubating under conditions that promote (i) hybridization between the tandem sequence DNA and the secondary DNA strand displacement primer, (ii) replication of the tandem sequence DNA (see column 46, lines 10-19);

With reference to the instant claims 85-106, 128-132, Kingsmore et al. teach that the method comprises detection labels as fluorescent moieties including fluorescent quenchers, which are incorporated into nucleic acids during amplification (see column 15, lines 55-67, column 16, lines 1-18).

With reference to the instant claims 108-112, Kingsmore et al. further teach that the method comprises (i) treating one or more analyte samples so that one or more samples modified

(see column 26, lines 15-48); bringing into contact one or more analytes and one or more arrays wherein each array comprises a set of analyte capture agents, a set of accessory molecules, each interacting directly or indirectly with an analyte, contacting one or more reporter binding molecules under conditions promoting interaction of the specific binding molecules analytes, analyte capture agents and accessory molecules, replicating with rolling circle replication primers to form tandem sequence DNA (see column 26, lines 50-67, column 27, lines 1-23); (ii) comprises solid support wherein components are immobilized to the solid support at a density exceeding 400 different components per cubic centimeter (see column 21, lines 8-19);

With reference to the instant claims 113-123, Kingsmore et al. also teach that the method comprises (i) analyte capture agents as peptides (see column 13, lines 59-66) immobilized on a solid support comprising 20% to 99% pure capture agents (see column 15, lines 5-20); (ii) comprises peptide, antibodies (antibodies are made up of short peptides) which comprise amino acids of about 20 amino acids (see column 13, lines 59-67, column 14, lines 1-11). Thus the disclosure of Kingsmore et al. meets the limitations in the instant claims.

However, Kingsmore et al. did not teach decoupling target circles from the reporter binding molecules, non-covalent interaction (base-pairing) of circle probe with reporter binding molecules and capture probe comprising oligonucleotide.

Lizardi et al. teach a rolling circle replication method using reporter systems wherein Lizardi et al. teach that the method comprises decoupling of amplification target circle from the reporter binding molecule (open circle probe) and the decoupling is facilitated by disrupting the base-pairing by exonuclease digestion (see col. 34, line 57-67, col. 35, line 1-16, col. 24, line 41-67, col. 26, line 32-35) or by heat denaturation (rising the temperature to disrupt base-pairing)

(see col.29, line 12-22). Lizardi et al. also teach that the method comprises detector probes (oligonucleotides) having a free 5' end or a free 3'-end and a label (reporter) coupled to the probes bounded either covalently or non-covalently to the component (see column 19, lines 32-41). Lizardi et al. also teach incorporation of peptide molecules into the probes with varying mass labels (see column 34, lines 21-56).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by Kingsmore et al. with a step of decoupling amplification target circle from reporter binding molecules method as taught by Lizardi et al, to develop a sensitive method for the detection of analyte(s) because Lizardi et al. taught the use decoupling of amplification target circle from the reporter binding molecule increases efficiency of secondary strand displacement, removes unligated probes, eliminates need for capture probes or washing steps (see col. 26, line 32-35, col. 35, line 8-16). An ordinary practitioner would have been motivated to combine the method of detecting one or more analytes as taught by Kingsmore et al. with the inclusion of the decoupling step as taught by Lizardi et al. in order to achieve the expected advantage of a developing a sensitive method for detecting analyte(s) because inclusion of such limitations would enhance the sensitivity of the detection method by reducing the background signal.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 12-113, 118-136 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6, 531, 283 in view of Lizardi et al. (USPN. 5,854,033).

The claims in the patent ('283) disclose and encompasses the instant method wherein the method in the patent comprises (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes (see column 41, lines 33-55); (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a single-stranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers (see column 41, lines 56-67); (d) incubating the rolling circle primers and amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes

(see column 42, lines 32-39). However the method in the patent ('283) did not specifically disclose a decoupling step to dissociate amplification target circle form reporter binding molecule.

Lizardi et al. teach a rolling circle replication method using reporter systems wherein Lizardi et al. teach that the method comprises decoupling of amplification target circle from the reporter binding molecule (open circle probe) and the decoupling is facilitated by disrupting the base-pairing by exonuclease digestion (see col. 34, line 57-67, col. 35, line 1-16, col. 24, line 41-67, col. 26, line 32-35) or by heat denaturation (rising the temperature to disrupt base-pairing) (see col.29, line 12-22). Lizardi et al. also teach that the method comprises detector probes (oligonucleotides) having a free 5' end or a free 3'-end and a label (reporter) coupled to the probes bounded either covalently or non-covalently to the component (see column 19, lines 32-41). Lizardi et al. also teach incorporation of peptide molecules into the probes with varying mass labels (see column 34, lines 21-56).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by the patent ('283) with a step of decoupling amplification target circle from reporter binding molecules method as taught by Lizardi et al, to develop a sensitive method for the detection of analyte(s) because Lizardi et al. taught the use decoupling of amplification target circle from the reporter binding molecule increases efficiency of secondary strand displacement, removes unligated probes, eliminates need for capture probes or washing steps (see col. 26, line 32-35, col. 35, line 8-16). An ordinary practitioner would have been motivated to combine the method of detecting one or more analytes as taught by patent ('283) with the inclusion of the decoupling

step as taught by Lizardi et al. in order to achieve the expected advantage of a developing a sensitive method for detecting analyte(s) because inclusion of such limitations would enhance the sensitivity of the detection method by reducing the background signal.

Therefore the instant claims are rejected under obviousness-type of double patenting.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
November 26, 2004

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
11/29/04